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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,919

04/16/2004

Alexander Deiters

54-000250US

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04/28/2010

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

P O BOX 458

ALAMEDA, CA 94501

EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

04/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,919	Applicant(s) DEITERS ET AL.	
	Examiner KAGNEW H. GEBREYESUS	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-54, 56-59, 63 and 64 is/are pending in the application.
- 4a) Of the above claim(s) 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-54, 56-59, 63-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 5, 2010 has been entered. Claims 1-51 were cancelled. Claims 53, 58, 63, and 64 are amended. Claim 62 has been withdrawn previously. Claims 52-54, 56-59, 63-64 are present for examination.

Sequence compliance

The specification is in compliance with 37 CFR 1.821-1-825 that require for each sequence present in the specification to be assigned a sequence identifier. The sequence listing now includes SEQ ID NO: 105, which represents the aminoacyl tRNA synthetase sequence comprising variable residues at positions 37, 126, 182, 183, and 186 of the aminoacyl tRNA synthetases.

Maintained - Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-54, 56-59, 63-64 remain rejected under 35 U.S.C. 112, first paragraph since the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention

Applicants argue:

“...Claim 63 was included in the §112 rejection regarding orthogonal aminoacyl tRNA synthetases comprising conservative amino acid substitutions, despite the fact that the claim does not contain any such language. Applicants are therefore unclear as to why claim 63 stands rejected and respectfully request clarification”

However claim 63 is rejected because the claim only recites an ORS that is “derived from an E.coli synthetase”, which is not limited to any structural characteristics and when broadly considered can read on any tRNA synthetase and variant thereof.

Applicants argue:

“...Amendments were made to claims 53 and 64 to clarify the language regarding conservative variants of amino acid sequences of the claimed orthogonal aminoacyl tRNA synthetases. Support for these amendments can be found throughout the specification, e.g., at paragraphs 0011, 0012, 0112, and 0113, and in original claim 42, which describe embodiments of amino acid sequences of orthogonal aminoacyl tRNA

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synthetases of the invention. Amendments were also made to claims 58 and 63 to correct minor punctuation errors...”

Applicant's argument has been carefully considered but not found persuasive for two reasons.

Applicants have amended claim 53 to encompass “O-RS molecules specific for p-propargyloxy-phenylalanine ...” where the structure of such ORS are not described (see 53 (i)).

Furthermore claim 53 (ii) recites: “... **an** amino acid set forth in any one of SEQ ID NO: 48-53 **and** conservative variants of SEQ ID NO: 48-53 where said sequences have at least 98% identity to SEQ ID NO: 48-53 or an amino acid sequence that is a conservative variant of SEQ ID NO: 2 (wild type *E. coli* tyrosyl tRNA synthetase) where said sequences have at least 98% identity to SEQ ID NO: 2 and comprises two or more variations at positions 37, 126, 182, 183 and 186 relative to the tyrosyl tRNA synthetase of *E. coli*.”

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The recitation: “...**an** amino acid sequence set forth in any one of SEQ ID NO: 48-53 **and** ...” lends a breadth that encompasses one or more amino acids residues from the polypeptide sequence of SEQ ID NO: 48-53 and any other additional amino acid residue(s). However the specification does not describe other ORS polypeptides that can accomplish the desired function(s).

In addition claim 52 recites: “an amino acid that corresponds to SEQ ID NO: 48-53”.

The specification teaches a method of producing in a eukaryotic cell a protein comprising an unnatural amino acid where the O-RS of SEQ ID NO: 48-53 that preferentially aminoacylate a corresponding O-tRNA with para-azido-L-phenylalanine where used. Furthermore the specification teaches said protein comprising the p-azidophenylalanine can be reacted to the unnatural amino acid p-propargyloxy-phenylalanine through a [3+2] cycloaddition reaction thereby modifying the protein (reaction between the two unnatural amino acids (azido-phenylalanine and the propargylphenylalanine)).

However the instant claims are drawn to a eukaryotic cells comprising a genus of O-RS molecules that preferentially aminoacylate structurally undefined O-tRNAs with p-propargylphenylalanines and where said cells further comprise a genus of O-RS molecules comprising "an amino acid that corresponds to SEQ ID NO: 48-53" (claim 52) or an amino acid sequence set forth in any one of SEQ ID NO: 48-53 and conservative variants of SEQ ID NO: 48-53 (claim 53) where said sequences have at least 98% identity to SEQ ID NO: 48-53 or **an** amino acid sequence that is a conservative variant of SEQ ID NO: 2 (wild type *E. coli* tyrosyl tRNA synthetase) where said sequences have at least 98% identity to SEQ ID NO: 2 and comprises two or more variations at positions 37, 126, 182, 183 and 186 relative to the tyrosyl tRNA synthetase of *E. coli* and preferentially aminoacylate structurally undefined O-tRNA molecules with p-azido-phenylalanine.

Furthermore the specification does not teach eukaryotic cells comprising a genus of O-RS molecules with different specificities that are co-expressed and preferentially

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aminoacylate O-tRNAs (structurally undefined) with p-azidophenylalanines and with p-propargylphenylalanine which are incorporated in a protein.

The disclosure of SEQ ID NO: 48-53 are insufficient to shed light on the broad scope of ORS molecules comprising any number of residues derived from SEQ ID NO: 48-53 and yet retain the capacity to aminoacylate an O-tRNA with p-azido-phenylalanine or p-propargyl-phenylalanine.

Furthermore applicants argue that the specific amino acid substitutions that correspond to specific positions shown in table 4, 6, and 8; and the guidance in the specification regarding methods of producing an O-RS that aminoacylate a cognate O-tRNA with p-azido-L-phenylalanine the guidance in the specification regarding conservative amino acid substitutions.....provide adequate description...”

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However while the specification provides guidance regarding for specific embodiments of the invention, the claims are not limited to such specific variants in view of the claim language and that the teachings of the specification cannot be concluded as claim limitations, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

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Conclusion: No claims are allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAGNEW H. GEBREYESUS PhD whose telephone number is (571)272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MANJUNATH RAO can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kagnew H Gebreyesus/
Examiner, Art Unit 1656

/ANAND U DESAI/
Primary Examiner, Art Unit 1656
4/23/2010.